K123478

510(k) Summary

Device Name

The device trade name and common/classifications name are:

Device Trade Name
Stingray Electrosurgical Forceps

Common Name
Bipolar Forceps

Classification Name
Electrosurgical cutting and coagulation device and accessories

Address, Registration #, and Contact Information

The address and registration number of the manufacturer site for the electrosurgical forceps is:

Manufacturer
Stingray Surgical Products LLC *156 NW 16 Street* *Boca Raton, FL 33432* FDA Registration #: *3006059917*

Contact Information
Name: Brian McBrinn *Position: Quality Manager* *Phone: (561) 210-7582* *Fax: (561) 210-5608* brian@stingraysurgical.com

Device Class and Classification

Stingray Electrosurgical Forceps have been classified as:

- Classification: Class II
- Classification Panel: General and Plastic Surgical Devices
- Product Code: GEI
- C.F.R Section: 878.4400

No performance standards have been established under Section 513/514 of the Food, Drug and Cosmetic Act for electrosurgical forceps.

Predicate Device Information

The predicate device is the Stingray Electrosurgical Forceps [K083162, concurrence date 01/12/2009].

Useful Life: The lifetime of the device has been best estimated based on the average age of devices returned for repair. When a device requires repair, it has exceeded its useful lifetime. Therefore the lifetime of the devices produced by Stingray Surgical Products LLC has been determined to be two (2) years. The performance characteristics of the device have been validated through twenty (20) sterilization cycles. Additional limit testing was conducted by subjecting the device to forty (40) sterilization cycles with no degradation observed. It is estimated that twenty sterilization cycles exceeds the estimated amount of cycles for a single device in use for two years.

Labeling and Intended Use

Draft "Instructions for Use" can be found in Attachment B.

No changes have been made to the device labeling and no modifications to the device labeling are included in this submission. Therefore no labeling has been provided within this submission.

Substantial changes to the Instructions for Use are proposed within this submission including a change of steam sterilization method and an update to the cleaning/reprocessing instructions. Additional instructions are proposed for cautions, precautions, use, handling, storage, warranty, and repair.

The intended use of the modified device, as described in its labeling, has not changed as a result of the modifications.

Intended Use:

Designed to grasp, manipulate and coagulate selected tissue for use in general surgical procedures. They are connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator. Bipolar forceps must only be used with bipolar coagulation current. Coagulation is achieved using electrosurgical energy generated by the electrosurgical generator unit and activated by a footswitch. The Stingray Forceps have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

This is the **same intended use** as previously cleared for the Stingray Electrosurgical Forceps, K083162.

The statement of Indications for Use can be found in section 6.

Device Description and Comparison

Device Description:

These devices are bipolar forceps design for use in general surgical procedures. They are connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator. The forceps are designed to grasp and manipulate selected tissues. Coagulation is achieved using electrosurgical energy generated by the electrosurgical generator unit and activated by a footswitch. They are constructed of stainless steel, a nylon coating, and a non-stick tip. The devices are provided non-sterile and must be autoclaved prior to use.

Comparison:

The Change Summary can be found in section 10 which provides the comparison to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 10, 2013

Stingray Surgical Products LLC
% Mr. Brian McBrinn
Quality Manager
156 NW 16th Street
Boca Raton, Florida 33432

Re: K123478
Trade/Device Name: Stingray Electrosurgical Forceps
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 09, 2013
Received: April 16, 2013

Dear Mr. McBrinn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123478

Device Name: Stingray Electrosurgical Forceps

Indications for Use:

Designed to grasp, manipulate and coagulate selected tissue for use in general surgical procedures. They are connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator. Bipolar forceps must only be used with bipolar coagulation current. Coagulation is achieved using electrosurgical energy generated by the electrosurgical generator unit and activated by a footswitch. The Stingray Forceps have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

Prescription Use _X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S

For

(Division Sign-Off)

Division of Surgical Devices

510(k) Number K123478